Sheet <u>1</u> of <u>12</u> Serial No. Atty. L. Lket No. U.S. Department of Commerce Form **PTO-1449** 60807-A-PCT-US 09/816,989 Patent and Trademark Office Applicants Alexander Gad et al. INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Group Art Unit Filing Date 1644 March 23, 2001 **U.S. PATENT DOCUMENTS** Filing Date Class Subclass Date Name **Document Number** Examiner if Appropriate Initial 11/19/74 Teitelbaum et al. US 3 Gaffar 13 7/13/82 US 4 Barbier et al. 4/20/93 0 US 9 6 1/7/97 Rodriguez et al. US Hupe et al. US 6 2 0 6 5/6/97 9/16/97 Shapiro et al. FOREIGN PATENT DOCUMENTS Translation Subclass Country Class **Document Number** Date Yes No 12/29/88 US WOI8 11/30/95 US wol9 3 12/14/95 Europe wol9 Ю 7/16/98 US WO|9 18 US WOI0 2/3/00 US 2/3/00 wolo. OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) "Suppression Experimental Allergid of Teitelbaum, al., et Encephalomyelitis by a Synthetic Polypeptide", Eur. J. Immunol. 1971, <u>1</u>, 242-248 Allergic "Suppression of Experimental al., Teitelbaum, et Encephalomyelitis by a Synthetic Polypeptide", <u>Israel J. Med</u> <u>Sci.</u>, 1971, <u>7</u>, 630-631 (Abstract) Experimental Allergic of "Suppression al., Encephalomyelitis by a Synthetic Copolymer Immunological Cross Reactive with Basic Encephalitogen", Israel J. Med. Sci., 8, 1759-1760 Teitelbaum, et al., "Protection Against Experimental Allergio Encephalomyelitis", <u>Nature</u>, 1972, <u>240</u>, 564-566 Webb, et al., "Further Studies on the Suppression of Experimental Allergic Encephalomyelitis by Synthetic Copolymer", Israel J. Med. <u>Sci.</u>, 1972, <u>8</u>, 656-657 DATE CONSIDERED **EXAMINER**

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicants: Alexander Gad and Dora Lis

Serial No.: 09/816,989 Filed: March 23, 2001

Exhibit C

Sheet 2 of 12

Serial No. Atty. Docket No. U.S. Department of Commerce Form PTO-1449 09/816,989 60807-A-PCT-US Patent and Trademark Office Applicants Alexander Gad et al. INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 **U.S. PATENT DOCUMENTS** Class Subclass Filing Date **Document Number** Date Name Examiner if Appropriate Initial 2/17/98 US Acton III, et al. 8 8 8 9/1/98 Konfino et al. US 5 8 1/12/99 Aharoni et al. US 5 11/9/99 Konfino et al. US 8 Hupe et al. US 9/28/99 8 US 4/11/00 Konfino et al. Ю 3 4/25/00 Konfino et al. US 6 4/10/01 Arnon et al. US 6 13 1/29/02 Konfino et al. US A1 12/27/01 Gilbert et al. 100 55 FOREIGN PATENT DOCUMENTS **Document Number** Date Country -Class Subclass Translation Yes No 4/6/00 US WO lo 2 Ю wolo Ю 0 Ю 4/13/00 US wolo. US 5/18/00 wolo-6 0 3 8/23/01 US wol0 9 3 12/13/01 IUS 12/27/01 US OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Experimental "Suppression of Allergid al., Teitelbaum. Encephalomyelitis with Basic Polymers", Eur. J. Immunol., 1973, 273-279 Webb, et al., "In Vivo and in Vitro Immunological Cross-reactions between Basic Encephalitogen and Synthetic Basic Polypeptides Capable of Suppressing Experimental Allergic Encephalomyelitis" <u>Eur. J. Immunol.</u>, 1973, <u>3</u>, 279-286 et al., "Dose-response Studies on Experimental Teitelbaum, Allergic Encephalomyelitis Suppression by COP-1", Israel J. Med. Sci., 1974, <u>10</u>(9), 1172-1173 DATE CONSIDERED EXAMINER

Atty. Licket No. Serial No. Form PTO-1449 U.S. Department of Commerce 09/816,989 60807-A-PCT-US Patent and Trademark Office Applicants Alexander Gad et al. INFORMATION DISCLOSURE CITATION (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 U.S. PATENT DOCUMENTS Filing Date Class Name Subclass **Document Number** Examiner if Appropriate Initial tus 10913 Strominger et al. 7/22/99 094 0 Gad et al. US 9/24/99 US 10918 6 9 3/23/01 Gad et al. 09 8 6/5/01 Yong and Chabot US Rodriguez and Ure US 09 8 6/20/01 FOREIGN PATENT DOCUMENTS **Document Number** Date Country Class **Subclass** Translation Yes No 8/22/90 Europe EΡ EP 11/29/95 Europe OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) al., Experimental Allergid Teitelbaum, et "Suppression of Encephalomyelitis in Synthetic Rhesus Monkeys by a Basid Copolymer", Clin. Immunol. Immunopath., 1974, 3, 256-262 Webb, "Suppression Allergic Experimental et al., of Rhesus Monkeys Encephalomyelitis in by a Synthetic Basid Copolymer", <u>Isr. J. Med. Sci.</u>, 1975, <u>11</u>, 1388 (Abstract) Webb, et al., "Molecular Requirements Involved in Suppression of EAE by Synthetic Basic Copolymers of Amino Acids", Immunochem., 1976, <u>13</u>, 333-337 Abramsky, et al., "Effect of a Synthetic Polypeptide (COP-1) on Patients with Multiple Sclerosis and with Acute Disseminated Encephalomyelitis", <u>J. Neurol. Sci.</u>, 1977, <u>31</u>, 433-438 Teitelbaum, al., "Suppression of Experimental et Encephalomyelitis in Baboons by Cop 1", Israel J. Med. Sci., 1977, 13, 1038 (Abstract) Arnon, et al., "Suppression of EAE in Baboons by a Synthetic Polymer of Amino Acids", <u>Neurol.</u>, 1978, <u>28</u>, 336 (Abstract) "Experimental Allergic Encephalomyelitis" et al., in Menarini Series on Immunopathology, vol. 1, First Symposium of Organ Specific Autoimmunity", Cremona, Italy, June, (Miescher P.A. ed., Schwabe Co., Basel, 1978), 9-21 Alvord, et al., "Myelin Basic Protein Treatment of Experimental Allergic Encephalomyelitis in Monkeys", Ann. Neurol., 1979, 6, 469-473 EXAMINER DATE CONSIDERED

Sheet 4 of 12 Serial No. Form PTO-1449 U.S. Department of Commerce Atty. Docket No. 09/816,989 Patent and Trademark Office 60807-A-PCT-US Applicants INFORMATION DISCLOSURE CITATION Alexander Gad et al. (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Keith, et al., "The Effect of COP 1, a Synthetic Polypeptide, on Chronic Relapsing Experimental Allergic Encephalomyelitis in Guinea Pigs" J. Neurol. Sci., 1979, 42, 267-274 Lando, et al., "Effect of Cyclophosphamide on Suppressor Cell Activity in Mice Unresponsive to EAE", J. Immunol., 1979, 123, 2156-2160 (Abstract) "Experimental Allergic Encephalomyelitis in Mice Lando et al., Suppression and Prevention with COP-1", Israel J. Med. Sci., 1979, 15, 868-896 (Abstract) Teitelbaum, et al., "Blocking of Sensitization to Encephalitogenic Basic Protein in Vitro by Synthetic Basic Copolymer (COP 1)" in Cell Biology and Immunology of Leukocyte Function (Academic Press, New York, 1979) 681-685 Teitelbaum, "Suppression of Experimental Allergic Encephalomyelitis with a Synthetic Copolymer - Relevance to Multiple Sclerosis", in Humoral Immunity in Neurological Diseases (Karcher D., Lowenthal A. & Strosberg A.D., eds., Plenum Publishing Corp., 1979) 609-613 "Desensitization of Experimental et al., Encephalomyelitis with Synthetic Peptide Analogues" in The Suppression of Experimental Allergic Encephalomyelitis and Multiple Sclerosis (Academic Press, New York, 1980) 105-107 Arnon, "A Synthetic Copolymer of Amino Acids in a Clinical Trial for MS Therapy" in <u>Progress in Multiple Sclerosis Research</u> (Bauer, Ritter, eds., Springer Verlag New York, 1980) 416-418 Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Ann. Neurol.</u>, 1980, <u>8</u>, 117 (Abstract) Bornstein, et al., "Treatment of Multiple Sclerosis with a Synthetic Polypeptide: Preliminary Results", <u>Trans. Am. Neurol. Assoc.</u>, 1980, <u>105</u>, 348-350 McDermott, et al., "Antigen-induced Suppression of Experimental Allergic

Neuritis in the Guinea Pig", <u>J. Neurol. Sci.</u>, 1980, <u>46</u>, 137-143

Arnon, "Experimental Allergic Encephalomyelitis - Susceptibility and Suppression", <u>Immunological Rev.</u>, 1981, <u>55</u>, 5-30

"Multiple of Synthetic Sclerosis: Trial Bornstein et al., Polypeptide", <u>Ann. Neurol</u>., 1982, <u>11</u>, 317-319

EXAMINER

DATE CONSIDERED

Sheet <u>5</u> of <u>12</u>

Form PTO-1449

U.S. Department of Commerce Patent and Trademark Office

INFORMATION DISCLOSURE CITATION

(Use several sheets if necessary)

Atty. Docket No. 60807-A-PCT-US

Serial No. 09/816,989

Applicants

Alexander Gad et al.

Filing Date March 23, 2001 Group Art Unit 1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Brosnan, et al., "The Response of Normal Human Lymphocytes to Copolymer 1", <u>J. Neuropath. Exp. Neurol.</u>, 1983, <u>42</u>, 356 (Abstract) Lisak, et al., "Effect of Treatment with Copolymer 1 (Cop-1) on the in Allergic Vitro Manifestations of Experimental and in Encephalomyelitis (EAE)", J. Neurol. Sci., 1983, 62, 281-293 Trials of Copolymer 1 Multiple "Clinical al., et Sclerosis", <u>Ann. N.Y. Acad. Sci. (USA)</u>, 1984, 366-372 Trials Synthetic Polypeptide "Clinical of a al., Bornstein, et (Copolymer 1) for the Treatment of Multiple Sclerosis" in Gonsett et al., Immunological and Clinical Aspects of Multiple Sclerosis (MTP Press, The Hague, 1984) 144-150 Brosnan, et al., "Copolymer 1: Effect on Normal Human Lymphocytes", Ann. N.Y. Acad. Sci. (USA), 1984, 436, 498-499 Bornstein, et al., "Multiple Sclerosis: Clinical Trials of a Synthetic Polypeptide, Copolymer 1", Neurol., 1985, 35 (Suppl. 1), 103 (Abstract) Brosnan, et al., "Immunogenic Potentials of Copolymer 1 in Normal Human Lymphocytes", <u>Neurol.</u>, 1985, <u>35</u>, 1754-1759 Burns, et al., "Human Cellular Immune Response in Vitro to Copolymer 1 and Myelin Basic Protein (MBP)", <u>Neurol.</u>, 1985, <u>35</u> (Suppl. 1), 170 (Abstract) Teitelbaum, et al., "Monoclonal Antibodies to Myelin Basic Protein Cross React with Synthetic EAE-suppressive Copolymer, COP 1" in Proc. 7th Eur. Immunol. Mtg., Jerusalem, September 8-13, 1985 (Abstract) Thompson, "MCQ Tutor: Medical Immunology Multiple Choice Questions", <u>Immunol. Today</u>, 1985, <u>6</u>(4), 141 Burns, et al., "Human Cellular Immune Response to Copolymer 1 and Myelin Basic Protein", <u>Neurol.</u>, 1986, <u>36</u>, 92-94 Bornstein, "Cop 1 May be Beneficial for Patients with Exacerbatingremitting Form of Multiple Sclerosis", Adv. Ther. (USA), 1987, 4, 206 (Abstract) Bornstein, et al., "A Pilot Trial of Cop 1 in Exacerbating-remitting Multiple Sclerosis", <u>New Eng. J. Med.</u>, 1987, <u>317</u>(7), 408-414 Multiple Sclerosis", Clin for Therapy "Copolymer-I Rolak, Neuropharmacology, 1987, <u>10</u>(5), 389-396 Winer, "COP 1 Therapy for Multiple Sclerosis", New Eng. J. Med., 1987, 442-444 DATE CONSIDERED EXAMINER

Form PTO-1449

U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. 60807-A-PCT-US 09/816,989

Applicants

Serial No.

INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)

Alexander Gad et al.

Filing Date Group Art Unit

March 23, 2001 1644

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Arnon, et al., "Suppression of Demyelinating Diseases by Synthetic Copolymers", in <u>A Multidisciplinary Approach to Myelin Disease</u> (G. Serlupi Crescenzi, ed., Plenum Publishing Corp., 1988) 243-250 Baumhefner, et al., "Copolymer 1 as Therapy for Multiple Sclerosis: The Cons", <u>Neurol.</u>, 1988, <u>38</u>(Suppl. 2), 69-71 al., "Clinical Experience with COP-1 Multiple Bornstein, et Sclerosis", <u>Neurol.</u>, 1988, <u>38</u>(Suppl. 2), 66-69 Teitelbaum, et al., "Specific Inhibition of the T-cell Response to Myelin Basic Protein by the Synthetic Copolymer Cop 1", Proc. Natl <u>Acad. Sci. USA</u>, 1988, <u>85</u>, 9724-9728 Arnon, et al., "Suppression of Experimental Allergic Encephalomyelitis by Cop-1 - Relevance to Multiple Sclerosis", Israel J. Med. Sci., 1989, 25, 686-689 Bornstein, et al., "Pilot Trial of COP-1 in Chronic Progressive Multiple from The International Multiple Sclerosis: Preliminary Report", Sclerosis <u>Conference: An Update on Multiple Sclerosis</u>, Roma (Italy), September 15-17, 1988, in <u>Elsevier Science Publisher</u>, 1989, 225-232 "Clinical Trial οf Copolymer 1 al., in Teitelbaum, et Sclerosis" <u>J. Israel Med. Assoc.</u>, 1989, <u>CXVI</u>(9), 453-456 Bornstein, et al., "Clinical Trials of Cop 1 in Multiple Sclerosis" in Handbook of Multiple Sclerosis (S.D. Cook Marcel Rekker, ed., 1990) 469-480 Carter, et al., "Newer Drug Therapies for Multiple Sclerosis", <u>Dru</u>q <u>Therapy</u>, 1990, 31-32, 37-39, 42-43 Grgacic, et al., "Cell-mediated Immune Response to Copolymer 1 Multiple Sclerosis Measured by the Macrophage Procoagulant Activity Assay", <u>Int. Immunol.</u>, 1990, <u>2</u>(8), <u>71</u>3-718 Kay, et al., "The Mechanism of Action of FK 506", Transplantation Proceedings, 1990, 22(1, Suppl. 1), 96-99 et al., "Peptide and Protein Drug Delivery" in Advances in Parenteral Sciences (Vincent H.L. Lee, ed., Marcel Dekker, Inc., 1990) 691-695

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Multiple Sclerosis", <u>Neurologic Clinics</u>, 1990, <u>8</u>(1), 119-141

to Multiple Sclerosis", <u>Bull. Inst. Pasteur</u>, 1990, <u>88</u>, 303-314

Myers, et al., "The Peculiar Difficulties of Therapeutic Trials for

Sela, et al., "Suppressive Activity of COP-1 in EAE and its Relevance

Sheet <u>7 of 12</u>

Serial No. Atty. Docket No. Form PTO-1449 U.S. Department of Commerce 09/816,989 60807-A-PCT-US Patent and Trademark Office Applicants INFORMATION DISCLOSURE CITATION Alexander Gad et al. (Use several sheets if necessary) Group Art Unit Filing Date March 23, 2001 1644 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Starzl, <u>Transplantation Proceedings</u>, 1990, <u>22</u> (1, Suppl. 1), 5 "Copolymer 1 (COP-1) in the Treatment of Multiple Sclerosis Wender, (letter)" Neur. Neurochir. Pol., 1990, 24, 113 Bornstein, et al., "A Placebo-controlled, Double-blind, Randomized Twocenter, Pilot Trial of Cop 1 in Chronic Progressive Multiple Sclerosis", <u>Neurol.</u>, 1991, <u>41</u>, 533-539 Burns, et al., "Failure of Copolymer 1 to Inhibit the Human T-cell Response to Myelin Basic Protein", Neurol., 1991, 41, 1317-1319 Clinical Trial Protocol No. 9001, Teva Pharmaceutical Industries, Ltd., first patient enrolled October 23, 1991 Ferrara, et al., "Graft-Versus-Host Disease", New Eng. J. Med., 1991, <u>324</u>, 667-674 "COP-1 Multicenter Clinical Trial in Exacerbating-remitting Meiner, Multiple-Sclerosis: One Year Follow-up", <u>J. Neurol.</u>, 1991(Suppl. 1) (Abstract) Rothbard, et al., "Interactions Between Immunogenic Peptides and MHC Proteins", <u>Ann. Rev. Immunol.</u>, 1991, <u>9</u>, 527-565 Salvetti, et al., "Myelin Basic Protein T Cell Epitopes in Patients with Multiple Sclerosis", Department of Neurological Sciences, University of Rome, La Sapienza 1991, 72 (Abstract) Teitelbaum, et al., "Cross-reactions and Specificities of Monoclonal Antibodies Against Myelin Basic Protein and Against the Synthetic Copolymer 1", <u>Proc. Natl. Acad. Sci. (USA)</u>, 1991, <u>88</u>, 9528-9532 Van den Bogaerde, et al., "Induction of Long-Term Survival of Hamster Heart Xenografts in Rats", <u>Transplantation</u>, 1991, <u>52</u>, 15-20 Bornstein et al., "Treatment of Multiple Sclerosis with Copolymer 1" in Treatment of Multiple Sclerosis: Trial Design, Results and Future Perspectives (Rudick R.A. & Goodkin D.E., eds., Springer Verlag, London, 1992, 173-198 Johnson, "Clinical Studies in Copolymer 1 Therapy for Exacerbatingremitting Multiple Sclerosis", in Congress for Advances in the Understanding and Treatment of Multiple Sclerosis, Boston (USA), Oct. 28-29, 1992 Milo, et al., "Inhibition of Myelin Basic Protein-specific Human T-cell Lines by COP-1", <u>Israel J. Med. Sci.</u>, 1992, <u>28</u>, 486 (Abstract) DATE CONSIDERED EXAMINER *EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next

communication to applicant.

Sheet <u>8 of 12</u>

Serial No. Form PTO-1449 U.S. Department of Commerce Atty. Docket No. 09/816,989 60807-A-PCT-US Patent and Trademark Office Applicants INFORMATION DISCLOSURE CITATION Alexander Gad et al. (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Racke, et al., "Copolymer-1-induced Inhibition of Antigen-specific T Interference with Antigen Presentation", Cell Activation: <u>Neuroimmunol.</u>, 1992, <u>37</u>, 75-84 Teitelbaum, et al., "Synthetic Copolymer 1 Inhibits Human T-cell Lines Specific for Myelin Basic Protein", Proc. Natl. Acad. Sci. (USA), 1992, <u>89</u>, 137-141 "Natural History and Treatment Multiple Weinshenker, et al., Sclerosis", Current Opinion in Neurol. and Neurosurgery, 1992, 5, 203-Aharoni, et al., "T Suppressor Hybridomas and Interleukin-2-Dependent Lines Induced by Copolymer 1 or by Spinal Cord Homogenate Down-Regulate Experimental Allergic Encephalomyelitis", <u>Eur. J. Immunol.</u>, 1993, <u>23</u>, 17-25 "Immunomodulation Allergid of Experimental Arnon, al., Encephalomyelitis", <u>Israel J. Med. Sci.</u>, 1993, <u>29</u>, 175-181 Arnon, et al., "On the Existence of Suppressor Cells", Int. Arch. <u> Allergy Immunol.</u>, 1993, <u>100</u>, 2-7 Clinical Trial Protocol No. 9002, Lemmon Co. and Teva Pharmaceutical Industries, Ltd., first patient enrolled June 17, 1993 Francis, "The Current Therapy of Multiple Sclerosis", J. Clin. Pharmacy <u>and Therapeutics</u>, 1993, <u>18</u>, 77-84 al., "Graft-versus-Host Disease in Bone Marrow Keleman, et Transplantation: Experimental, Laboratory, and Clinical Contributions of the Last Few Years", <u>Int. Arch. Allergy Immunol.</u>, 1993, <u>102</u>, 309-320 Gurevich, "Study of the MHC-competition Between BP and Cop 1 Using Human Cytotoxic T-cell Clones", <u>Israel J. Med. Sci.</u>, 1993 (Abstract) "The Israeli COP-1 Multicenter Clinical in Meiner et al., Exacerbating-remitting Multiple Sclerosis - Two year Follow-up", in 9th Congress of the European Committee for Treatment and Research (Italy), October-November, Multiple Sclerosis, Florence (Abstract) Milo, et al., "Copolymer-1 (COP-1) Regulates Class II MHC Expression and Cytokine Synthesis in the THP-1 Monocyte-Macrophage Cell Line" in The IBC Conference on Multiple Sclerosis, San Diego (USA), December 10, 1993 (Abstract) DATE CONSIDERED EXAMINER

Serial No. Form **PTO-1449** U.S. Department of Commerce Attv. Docket No. 09/816,989 Patent and Trademark Office 60807-A-PCT-US Applicants INFORMATION DISCLOSURE CITATION Alexander Gad et al. (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) "Polymeric Drugs as Immunomodulatory Vaccines Against Multiple Sela, Sclerosis", Makromol. Chem. Macromol. Symp., 1993, 70/71, 147-155 Arnon, et al., "Immunospecific Drug Design - Prospects for Treatment of Autoimmune Disease", <u>Therapeutic Immunol.</u>, 1994, <u>1</u>, 65-70 "Multiple Sclerosis: Pathogenesis and Treatment", al., <u>Seminars in Neurol.</u>, June 1994, <u>14</u>(2), 146-153 The COP-1 Multicenter Clinical and Research Group Study, Multicenter Trial in Relapsing Remitting Multiple Sclerosis: 3 Year Follow Up", <u>Abstracts of Symposia and Free Communication</u>, Barcelona (Spain), June 25-29, 1994, 241 (Suppl. 1), 6 Cotton, "Options for Multiple Sclerosis Therapy", J.A.M.A. Medical News <u>& Perspectives</u>, 1994, <u>272</u>(18), 1393 Dorling, et al., "Prospects for Xenografting", Curr. Opinions Immunol. 1994, <u>6</u>, 765-769 Fridkis-Hareli, et al., "Copolymer 1 Displaces MBP, PLP and MOG, but Can Not be Displaced by these Antigens from the MHC Class II Binding Site", Department of Chemical Immunology, The Weizmann Institute of Science, 1994 Fridkis-Hareli, et al., "Direct Binding of Myelin Basic Protein and Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Specificity on Living Antigen-Presenting Cells Molecules Promiscuity", Proc. Natl. Acad. Sci. USA, 1994, 91, 4872-4876 Fridkis-Hareli, et al., "Specific and Promiscuous Binding of Synthetic Copolymer 1 to Class II Major Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Israeli Biochem. Soc.</u>, 1994, 21-22 (Abstract) Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells" in Neurochem Mtg., August 14-19, 1994 Fridkis-Hareli, et al., "Synthetic Copolymer 1 Inhibits the Binding of MBP, PLP and MOG Peptides to Class II Major Histocompatibility Complex Molecules on Antigen- Presenting Cells", <u>J. Neurochem.</u>, 1994, <u>63</u>(Suppl. I), 561 Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Require Processing Prior to Binding to Class Histocompatibility Complex Molecules on Living Antigen Presenting Cells", <u>Department of Chemical Immunology. The Weizmann Institute of</u> <u>Science</u>, Rehovot, Israel, 1994

EXAMINER

DATE CONSIDERED

Sheet <u>10</u> of 12 Serial No. Form **PTO-1449 U.S.** Department of Commerce Atty. Docket No. 09/816,989 Patent and Trademark Office 60807-A-PCT-US Applicants INFORMATION DISCLOSURE CITATION Alexander Gad et al. (Use several sheets if necessary) Filing Date Group Art Unit March 23, 2001 1644 OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Require Processing Prior to Binding to Class Histocompatibility Complex Molecules on Living Antigen-Presenting Cells", <u>Cell. Immunol.</u>, 1995, <u>163</u>, 229-236 Fridkis-Hareli, et al., "Synthetic Copolymer 1 and Myelin Basic Protein Do Not Undergo Processing Prior to the Binding to Class II Major Histocompatibility Complex Molecules on Antigen Presenting Cells", Israeli Immunol. Soc., May 3-4, 1994 (Abstract) Jacobs, et al., "Advances in Specific Therapy for Multiple Sclerosis", <u>Neurol.</u>, 1994, <u>7</u>, 250-254 Johnson, "Experimental Therapy of Relapsing-Remitting Multiple Sclerosis with Copolymer-1", <u>Ann. Neurol.</u>, 1994, <u>36</u>(Suppl.), 115-117 Kott, et al., "COP-1 Increases Suppressor Cells Number in Multiple Sclerosis", <u>Israel Neurological Assoc.</u>, December 19-20, 1994, Herzliya (Israel), 17 Mengle-Gaw, "The Major Histocompatibility Complex (MHC)", in Encycl Molecular Bio. (Oxford Blackwell Science Ltd, 1994) 602-606 Milo, et al., "Additive Effects of COP-1 and IFN-Beta on Immune Responses to Myelin Basic Protein", Neurol., 1994, 44 (Suppl. 2), A212 Milo et al., "Additive Effect of Copolymer-1 and Interferon-B on the Immune Response to Myelin Basic Protein", Assaf Harofeh Medical Center, Sackler School of Medicine, Tel-Aviv University of Maryland School of Medicine, 1994, 22 Milo, et al., "Copolymer-1 and Interferon-β Additively Suppress the Response to Myelin Basic Protein by Inhibiting Presentation", <u>J. Neuroimmunol.</u>, 1994, <u>54</u>, 183 (Abstract) Nightingale, et al., "Access to Investigational Drugs for Treatment Purposes", <u>Am. Family Physician</u>, 1994, <u>50</u>(4), 845-847 Tisch et al., "Antigen-specific immunotherapy: Is it a Real Possibility to Combat T-Cell-Mediated autoimmunity?" <u>Proc. Natl. Acad. Sci. U.S.A</u>., 1994, <u>91</u>, 437-438

Schlegel, et al., "Prevention of Graft-Versus-Host Disease by Peptides Binding to Class II Major Histocompatibility Complex Molecules", <u>Blood</u>, 1994, <u>84</u>(8), 2802-2810

Stark, "Expanded Clinical Trials of Treatments for Multiple Sclerosis (MS): Copolymer 1 (COP-1) Treatment Investigational New Drug (IND) Program", <u>Ann. Neurol.</u>, 1994, <u>36</u>, 114-115

EXAMINER

DATE CONSIDERED

				Sheet <u>11 of 12</u>	
		U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 60807-A-PCT-US	Serial No. 09/816,989	
		IATION DISCLOSURE CITATION	Applicants Alexander Gad et al.		
	. ((Use several sheets if necessary)	Filing Date March 23, 2001	Group Art Unit 1644	
	O	THER DOCUMENTS (Including Author, Title, Do	ate, Pertinent Pages, E	Etc.)	
	Trial of	num, et al., "Immunological Paramet COP1 in Multiple Sclerosis (MS): L(Suppl. 2), A358			
		al., "Additive Effects of Copoly une Response to Myelin Basic Prote 193			
		r, et al., "Powders" in <u>The Scien</u> on, 1995, <u>2</u> , 1598-1614	nce and Practic	e of Pharmacy,	
	Porter, "Coating of Pharmaceutical Dosage Forms," in <u>The Science and Practice of Pharmacy</u> , Remington, 1995, <u>2</u> , 1650-1659				
	Reilly, Jr., W.J., "Pharmaceutical Necessities" in <u>The Science and Practice of Pharmacy</u> , Remington 1995, <u>2</u> , 1380-1416				
	Graft-vs Promiscu Soc. Hem	l, et al., "Inhibition of Allores-host Disease (GVHD) by GLAT, lous Binding to Murine and Human Mi matology, 37 th Annual Meeting, Sea 24a (Abstract)	a Synthetic HC Class II Mole	Polymer with ecules", in <u>Am.</u>	
	Glycopro Effect	et al., "The Autoimmune Reactive stein (MOG)in Multiple Sclerosis of Copolymer 1 on MOG-induced ol. 1), S14-S22	s is Potential	ly Pathogenic:	
		Management of Relapsing/Remitter 1 (Copaxone)", Chemical Abstrac			
	Sykes, "	Immunobiology of Transplantation"	, <u>Faseb J.</u> , 199	96, <u>10</u> , 721-730	
	Allergic in Mice	um, et al., "Copolymer 1 Inhibits of Encephalomyelitis Induced by Prote and Interferes with PLP-spectrunol., 1996, <u>64</u> , 209-217	eolipid Protein	(PLP) Peptides	
	of the S	et al., "Studies on the Mechanism Synthetic Random Copolymer GLAT o <u>Letters</u> , 1997, <u>58</u> , 79-87			
		al., "Modulation of the Immune Res ol., 1997, <u>158</u> , 2471-2476	sponse in Multi	ple Sclerosis",	
	Treatmen	et al., "Copolymer 1 (Copaxone) it of Multiple Sclerosis" Databas 270. Kim, Handasa Kim, 1997, <u>281</u> (se HCAPLUS on S	STN, Israel: AM	

EXAMINER

DATE CONSIDERED

Sheet 12 of 12

Form PTO-1449	U.S. Department of Commerce Patent and Trademark Office	Atty. Docket No. 60807-A-PCT-U	Serial No. 09/816,989	
INFORM	MATION DISCLOSURE CITATION	Applicants Alexander Gad		
J)	Use several sheets if necessary)	Filing Date March 23, 2001	Group Art Unit 1644	
ОТ	THER DOCUMENTS (Including Author, Title,	Date, Pertinent Pages	, Etc.)	
	um, et al., "Copolymer 1 from th ., 1997, <u>33</u> , 280-284	ne Laboratory to	FDA", <u>Israel</u> J	
Fridkis- to Purif	Hareli, et al., "Promiscuous Bi ied HLA-DR Molecules", <u>J. Immun</u>	inding of Synthe ol., 1998, <u>160</u> ,	etic Copolymer 1 4386-4397	
HLA-DR P	Hareli, et al., "Synthetic Amin Proteins and Inhibit Type II Co tl. Acad. Sci., 1998, <u>95</u> , 12528	llagen-Reactive	ers that Bind to T Cell Clones"	
Durelli,	"Immunotherapeutics of Multipl delle Malattie del Sistema Nerv	e Sclerosis", <u>I</u>	<u>nstituto di</u> di Torino, 467-	
			· ·	
	· · · · · · · · · · · · · · · · · · ·			
		<u> </u>		
		· · · · · · · · · · · · · · · · · · ·		
	·			
EXAMINER	DATE CONSIDERED			